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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,778	04/20/2001	James N. Herron	3278.1US	3373

24247 7590 12/31/2003

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,778	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackowski, 5,747,274. Jackowski discloses a method evaluating the presence of a plurality of analytes in a sample, at least one analyte having known parameters indicative of an acute metabolic or disease state, see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14; substantially simultaneously determining concentrations of each of the analytes; continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see column 29, lines 51-63; and reporting said determination in an amount indicative of the metabolic or disease state, see column 29, lines 51-63.

As to claim 2, evaluating the presence of at least one other analyte continues after the report in order to accurately determine the presence or concentration of the analyte, see column 22, lines 1-12.

As to claim 3, the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points, see column 22, lines 6-12.

As to claim 4, the determination is effected by reacting at least one analyte with a corresponding reactive element, see column 19 lines 15-22.

As to claim 5, the determination includes exposing the sample to the reactive elements, see column 11, lines 1-12.

As to claim 6, each reactive element is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claims 7 and 12, the continuation includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, see column 2, lines 53-59, see column 29, lines 50-55, and column 32, lines 19-31.

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the reactive element has coupled with the analyte, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 10, the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 11, the determination includes measuring the light signal generated from the reaction of the analyte with the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction, see column 1, lines 63-67.

As to claim 14, the marker comprises myoglobin, see column 4, line 36-5.

As to claim 15, the analyte is a cardiac specific marker, see column 1, lines 63-67.

As to claims16-19, the analyte comprises troponin as claimed, see column 7, lines 34-37.

As to claim 20, the analyte comprises creatine kinase, see column 5, lines 29-31.

As to claim 21, the creatine kinase comprises CK-MB, see column 5, lines 29-31.

Response to Arguments

Applicant's arguments filed September 30, 2003 have been fully considered but they are not persuasive.

Applicant argues on page 7 that Jackowski fails to disclose the elements of "continuing the substantially simultaneous determination until the at least one analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state," but instead, Jackowski discloses a method for making a single determination occurring at a single point in time, not continuing a single assay.

In response, Examiner points to column 22, lines 13-19, in Jackowski, wherein it is disclosed that the sample in which the level of each marker is assessed is from a sample drawn at a single point in time, and that the markers can be measured in a single device or in separate devices. Jackowski also discloses that simultaneous means that the analysis must be done within a time frame, see column 22, lines 7-8. Thus, the detection of a marker, one after another, from a single sample, results in "continuing the substantially simultaneously determination" as claimed by Applicant.

Applicant also points to column 32, lines 27-32, in Jackowski, to show that the Jackowski method is directed to repetition of a single time point assays with different samples at different times. Examiner agrees that Jackowski discloses this. However, this is just another diagnostic method disclosed by Jackowski. Jackowski also discloses use of a single sample as explained immediately above, which is used in the above rejections.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Mary E. Ceperley
MARY E. CEPERLEY
PRIMARY EXAMINER
AU 1641

A.L.